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Registration Decision RD2015-28

Autographa californica Nucleopolyhedrovirus FV11

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Registration Decision for *Autographa californica* nucleopolyhedrovirus FV11

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of AcMNPV Technical and Loopex, containing the technical grade active ingredient *Autographa californica* nucleopolyhedrovirus FV11, to control cabbage looper larvae in greenhouse cucumber, peppers and tomatoes.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2015-09, *Autographa californica* nucleopolyhedrovirus FV11. This Registration Decision[2] describes this stage of the PMRA's regulatory process for *Autographa californica* nucleopolyhedrovirus FV11 and summarizes the Agency's decision, and the reasons for it. The PMRA received no comments on PRD2015-09. This decision is consistent with the proposed registration decision stated in PRD2015-09.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2015-09, *Autographa californica* nucleopolyhedrovirus FV11 that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "... the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is *Autographa californica* nucleopolyhedrovirus FV11?

Autographa californica nucleopolyhedrovirus FV11 is the active ingredient in AcMNPV Technical and Loopex. Loopex is a new end-use product that is proposed for use as commercial-class biological insecticide for the control of cabbage looper (*Trichoplusia ni*) larvae on greenhouse grown cucumbers, peppers and tomatos. Loopex is applied as a foliar spray.

Autographa californica nucleopolyhedrovirus FV11 is a naturally occurring baculovirus within the genus *Alphabaculovirus*. It has a host range limited to the larvae of several species of Lepidoptera within the family Noctuidae, including the cabbage looper *Trichoplusia ni*. The baculovirus polyhedral inclusion bodies (PIBs) must be ingested by the larvae in order to be effective. Upon ingestion, the virus replication process is initiated. Virus-infected cells produce non-occluded virus, which spreads infection throughout the host. The virus-infected larva eventually disintegrates and releases new occluded virus particles which may infect other larvae upon ingestion.

Health Considerations

Can Approved Uses of *Autographa californica* nucleopolyhedrovirus FV11 Affect Human Health?

***Autographa californica* nucleopolyhedrovirus FV11 is unlikely to affect your health when Loopex is used according to the label directions.**

People could be exposed to *Autographa californica* nucleopolyhedrovirus FV11 when handling and applying Loopex, and when ingesting treated produce. When assessing health risks, several key factors are considered:

- the microorganism's biological properties (for example, infection cycle);
- reports of any adverse incidents;
- its potential to cause disease or toxicity as determined in toxicological studies; and
- the level to which people may be exposed relative to exposures already encountered in nature to other isolates of this microorganism.

Toxicological studies in laboratory animals describe potential health effects from large doses in order to identify any potential pathogenicity, infectivity and toxicity concerns. When other strains of *Autographa californica* nucleopolyhedrovirus or other baculoviruses were tested on laboratory animals and tissue cultures, there were no signs that it caused any significant toxicity or disease. Furthermore, there have been no reported adverse effects despite the natural occurrence and prevalence of baculoviruses in the environment and the limited host range associated with baculoviruses has been well documented.

Residues in Water and Food

Dietary risks from food and water are not of concern.

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether the consumption of the maximum amount of residues, that are expected to remain on food products when a pesticide is used according to label directions, will not be a concern to human health. This maximum amount of residues expected is then legally established as a maximum residue limit (MRL) under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*. Health Canada specifies science-based MRLs to ensure that the food Canadians eat is safe.

Residues of *Autographa californica* nucleopolyhedrovirus FV11 on treated food crops, at the time of harvest, are anticipated following foliar applications to agricultural crops. While baculoviruses are not commonly found on food crops, they are abundant in nature; however, no adverse effects from dietary exposure have been attributed to natural populations of *Autographa californica* nucleopolyhedrovirus. Moreover, no adverse effects have been reported in acute oral toxicity and tissue culture studies with other strains of *Autographa californica* nucleopolyhedrovirus or with other studied baculoviruses. In addition, the likelihood of residues contaminating drinking water supplies is negligible to non-existent. Consequently, dietary risks are considered to be negligible and not of concern. Therefore, the Pest Management Regulatory Agency (PMRA) has determined that specification of an MRL under the *Pest Control Products Act* is not required for *Autographa californica* nucleopolyhedrovirus FV11.

Risks in Residential and Other Non-Occupational Environments

Estimated risk for non-occupational exposure is not of concern.

Loopex is proposed for use on greenhouse grown agricultural crops. Consequently, it is unlikely that adults, youths and toddlers will be exposed to *Autographa californica* nucleopolyhedrovirus FV11. Even in the event of exposure, risk to the general population is not a concern since there were no signs of disease or toxicity noted in toxicological studies with other strains of *Autographa californica* nucleopolyhedrovirus (AcMNPV) or other baculoviruses.

Occupational Risks From Handling Loopex

Occupational risks are not of concern when Loopex is used according to label directions, which include protective measures.

Workers handling Loopex can come into direct contact with *Autographa californica* nucleopolyhedrovirus FV11 on the skin, in the eyes or by inhalation. For this reason, the product label will specify that workers exposed to the end-use product must wear a long-sleeved shirt, long pants, shoes plus socks, waterproof gloves, eye goggles and a NIOSH approved mist filtering mask or respirator with any N-95, P-95 or R-95 filter. In addition, all unprotected workers are restricted from entering enclosed areas (including greenhouses) where Loopex has been applied until mists have settled.

For the bystander, exposure is expected to be much less than that of handlers and mixer/loaders and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When *Autographa californica* nucleopolyhedrovirus FV11 Is Introduced Into the Environment?

Environmental risks are not of concern.

Autographa californica nucleopolyhedrovirus FV11 is a baculovirus that specifically infects lepidoteran insects.

Loopex is proposed for use as an insecticide to control cabbage looper larvae in greenhouse grown cucumbers peppers and tomatoes and is not intended for aquatic applications. Exposure to outdoor terrestrial and aquatic environments is expected to be minimal.

Acceptable scientific rationales were used to determine that no significant adverse effects to non-target organisms are expected.

Value Considerations

What Is the Value of Loopex?

Loopex controls cabbage looper larvae in greenhouse tomato, cucumber and pepper.

Foliar applications of Loopex control cabbage looper larvae on listed greenhouse crops. Applications should target small larvae. Applications may be repeated every 7-14 days as long as monitoring indicates they are necessary.

Resistance to *Autographa californica* nucleopolyhedrovirus FV11 in cabbage looper has not been reported. *Autographa californica* nucleopolyhedrovirus FV11 represents a new mode of action for use against cabbage looper larvae. Based on the demonstrated efficacy of the product and its compatibility with *Bacillus thuringiensis* (Bt) treatment, chemical insecticides and beneficial insect species, Loopex could be a valuable part of an integrated pest management program on greenhouse tomato, cucumber and pepper. Registration in Canada would address three priorities listed in the Canadian Grower Priority Database.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Loopex to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

In individuals exposed repeatedly to potentially large quantities of Loopex, respiratory and dermal sensitivity may possibly develop. All microorganisms, including *Autographa californica* nucleopolyhedrovirus FV11, contain substances that are potential sensitizers. Therefore, anyone handling or applying Loopex must wear appropriate personal protective equipment including a long-sleeved shirt, long pants, shoes plus socks, waterproof gloves, eye goggles and a NIOSH approved mist filtering mask or respirator with any N-95, P-95 or R-95 filter. In addition, all unprotected workers are restricted from entering enclosed areas (including greenhouses) where Loopex has been applied until mists have settled.

Environment

The end-use product label will include environmental precaution statements that prevent the contamination of aquatic systems from the use of Loopex.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2015-09, *Autographa californica* nucleopolyhedrovirus FV11*)* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

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5 As per subsection 35(1) of the *Pest Control Products Act*.